DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 6, 2015

Integra Lifesciences Corporation
Janet Kay
Director, Regulatory Affairs
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K140722
Trade/Device Name: OSV II Valve Systems, Integra Flow Regulating Valve Low Flow Valve Systems
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: December 22, 2014
Received: December 24, 2014

Dear Ms. Kay,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140722

Device Name
OSV II Valve Systems
Integra Flow Regulating Valve Low Flow Valve Systems

Indications for Use *(Describe)*
Models for ventricular application:
The Integra Flow Regulating Valve Systems are implantable systems used in the treatment of patients with hydocephalus, to shunt CSF from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium.

Models for lumbar application:
The Lumbar Integra Flow Regulating Valve Systems are implantable systems used in the treatment of patients with communicating hydrocephalus to shunt CSF from the lumbar subarachnoid region to the peritoneal cavity.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	22 Terry Avenue Burlington, MA 01830
Phone Number	(781) 565-1347
Fax Number	(781) 238-0645
Establishment Registration Number	1222895
Name of Contact Person	Janet Kay
Date Prepared	January 5, 2015
807.92(a)(2) – Name of device	
Trade or Propriety Names	OSV II® Valve Systems Integra Flow Regulating Valve Low Flow Valve Systems
Common or Usual Name	Hydrocephalus Shunt System and Components
Classification Name	Central Nervous System Fluid Shunt and Components
Classification Panel	Neurology
Regulation	Class II, under 21 CFR 882.5550
Product Code(s)	JXG
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
Equivalence is claimed to current Integra Flow Regulating Valves cleared under the following Premarket Notifications: K042192 - Integra Flow Regulating Valve Low Flow (Standard) K081773 – OSV II and OSV II Low Pro K093968- Integra Flow Regulating Valve Low Flow (Mini) K092395 - OSV II Lumbar and Integra Flow Regulating Valve Low Flow (Lumbar)	
807.92(a)(4) - Device description	
The Integra Flow Regulating Hydrocephalus Valve Systems are implantable devices for controlled cerebrospinal fluid (CSF) drainage from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium (ventricular application) or from the lumbar subarachnoid region to the peritoneal cavity (lumbar application). Unlike conventional valves, these are variable resistance valves which maintain a drainage rate constant within the physiological range (for the specified populations and disorders) of intracranial pressure. The mechanism incorporates a safety pressure relief mode to prevent accidental intracranial hypertension. The various models include two flow regulating ranges, two antechamber sizes, and	

various accessories allowing either a ventricular or a lumbar application. The two flow regulating ranges are:

Standard flow regulating: maintains a drainage rate close to the normal CSF secretion rate, around 20ml/hr (18-30ml/h).

Low flow regulating: maintains a lower drainage rate than OSV II Valve Systems, around 10ml/hr (8-17ml/h).

The systems are available in different configurations. A system generally consists of a ventricular or lumbar (proximal) catheter, a valve unit, and a drainage (distal) catheter. Some configurations contain an antechamber (standard or low profile) or a burr hole cap.

Various accessories are available for the implantation procedure or to be implanted in addition to the valves.

All products are sold sterilized, for single use only

807.92(a)(5) – Intended use of the device

Indications for Use	Models for ventricular application: The Integra Flow Regulating Valve Systems are implantable systems used in the treatment of patients with hydrocephalus, to shunt CSF from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium. Models for lumbar application: The Lumbar Integra Flow Regulating Valve Systems are implantable systems used in the treatment of patients with communicating hydrocephalus to shunt CSF from the lumbar subarachnoid region to the peritoneal cavity.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

The modified devices have the same design, materials (except a change of epoxy glue), indications, contraindications, packaging, manufacturing and sterilization processes as the predicate devices. There is no change to the products except for the epoxy glue.

807.92(b)(1-2) – Nonclinical tests submitted

The following tests were performed and described below. Samples were environmentally conditioned, aged, and 2x sterilized by Ethylene Oxide.

Load Testing
Load testing was conducted up to 15N (1.5kg).

Water Test

Water testing was conducted at 37^0C for 28 days.

Biocompatibility testing

The biocompatibility evaluation for the modification to the Integra Flow Regulating Valve Systems (Integra Flow Regulating Valve Low Flow (Standard), OSV II and OSV II Low Pro and Integra Flow Regulating Valve Low Flow (Mini)) and the Lumbar Integra Flow Regulating Valve Systems (OSV II Lumbar and Integra Flow Regulating Valve Low Flow (Lumbar)) devices were conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

Sensitization	ISO 10993-10:2010
Genotoxicity	
Bacterial Reverse Mutation Study	ISO 10993-3:2003
In Vitro Chromosomal Aberration Study in Mammalian Cells	ISO 10993-3:2003
Mouse Peripheral Blood Micronucleus Test	ISO 10993-3:2003
Pyrogen	
Rabbit Pyrogen Study	USP35, NF30<151>

The flow regulating valve systems are considered implantable devices, tissue and/or bone contacting and are permanent implants (>30 days). The biocompatibility testing and design verification testing have verified that the change of glue has no impact on the product specifications, performance and reliability.

Additional testing was conducted and concluded to the MR Conditional status of the valves. The battery of testing included the following tests:

Radio Frequency Induced Heating Test	ASTM F2182-09
MR Image Artifacts	ASTM F2119-07
Magnetically Induced Displacement Force test	ASTM F2052-06e1
Magnetically Induced Torque Test	ASTM F2213-06

807.92(b)(3) – Conclusions drawn from non-clinical data

The predicate devices were cleared based on the results of non-clinical data. The modified devices and predicate device performance data were compared to support the safety of the modified devices and demonstrate that the Integra Flow Regulating Hydrocephalus Valve Systems should perform as intended in the specified use conditions.